



Status of Aquaculture Drug Approvals

prepared
by

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Background information



- ▶ Graphs represent AADAP's interpretation and condensation of matrices produced by the National Coordinator for Aquatic New Animal Drug Applications (Ms. Rosalie Schnick)
 - ▶ Matrices in full detail available at:
 - ▶ <http://aquanic.org/jsa/aquadrugs/index.htm> and
 - ▶ <http://www.fws.gov/fisheries/aadap/status.htm>
- ▶ Interpretive methods
 - ▶ categorically assigned a status number to each subsection of the 5 major NADA technical sections (efficacy, target animal safety, environmental safety, human food safety and manufacturing chemistry)
 - ▶ calculated overall estimated percent complete, based on means



Abbreviations and Footnotes

- EFF = efficacy technical section (TS)
- TAS = target animal safety TS
- MC = manufacturing chemistry TS
- HFS = human food safety TS
- ES = environmental safety TS
- all = all major TS (i.e., EFF, TAS, MC, HFS & ES)
- NADA = New Animal Drug Application *per se*
- * = any number on the graph with an asterisk is a value from Sept 2006
- label = actual approved drug label with associated claims
- AOI = all other information required for a complete NADA
- deficient = TS has not been completely accepted by CVM
- ★ = you may be able to generate data to help complete this TS



Updated: 25 May 2007

Technical Section	Entity—Data—Action	Impediments or Cost—Action
Product Chemistry	UMESC (IAD #8086)—Product Chemistry—submitted to CVM 5/22/06	None—pending acceptance
Environmental Safety (flow-through)	UMESC (PMF #5637)—Validation of dilution model—accepted 5/7/03	None—model accepted
Environmental Safety (flow-through/all freshwater-reared finfish)	UMESC (IAD #10-874)—Environmental assessment/flow-through systems/all freshwater-reared finfish—revision submitted to CVM 2/8/06, submitted external EA #13187	None—pending acceptance
Human Food Safety/Toxicology	AAC (IAD #8086)—Toxicology/genotoxicity studies—accepted 7/1/04	None
Human Food Safety/Toxicology	AAC (IAD #8086)—Toxicological mammalian safety—accepted 4/9/03	None—This portion of the Technical Section is complete
Human Food Safety—Residue Chemistry (analytical method in water (all finfish))	UMESC (PMF #5637)—Residue Chemistry/analytical method in water for	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/white striped bass—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/yellow perch—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (marker residue depletion)	UMESC (PMF #5637)—Residue chemistry/marker residue depletion/rainbow trout—accepted 4/23/02	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (regulatory method developed)	UMESC (PMF #5637)—Residue chemistry/regulatory method developed: TBA/rainbow trout, channel catfish, & walleye—accepted 4/24/03	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (regulatory method validated)	UMESC (PMF #5637)—Residue chemistry/regulatory method validated: TBA/all freshwater-reared finfish—accepted 4/15/04	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Residue Chemistry (confirmatory method)	CVM-OR—Residue Chemistry/confirmatory method/freshwater-reared finfish funded by UMESC—accepted 3/4/05	None—all residue chemistry data accepted for all freshwater-reared finfish
Human Food Safety—Microbial Food Safety (all freshwater-reared finfish)	AAC (IAD #8086) & NADA Coordinator—Microbial food safety (Guidance Document #152/all freshwater-reared finfish)—accepted 5/07	None
Human Food Safety—Microbial Food Safety (all freshwater-reared finfish)	AAC (IAD #8086) & NADA Coordinator—Microbial food safety (Guidance Document #159/all freshwater-reared finfish)—submitted 1/106	None—pending acceptance
Target Animal Safety (all coolwater & warmwater finfish)	UMESC (PMF #5637 & IAD #10-874)—Target Animal Safety/all coolwater & warmwater fish—accepted 3/11/04 & 3/11/05	None—This Technical Section is complete for all freshwater-reared finfish
Target Animal Safety (all freshwater-reared salmonids)	AADAP (IAD #4000 & #9321)—Target animal safety/all salmonids—accepted 8/13/02	None—This Technical Section is complete for all freshwater-reared finfish
Efficacy (external columnaris disease/walleye)	UMESC (PMF #5637 & IAD #10-874)—Efficacy/external columnaris disease/walleye—accepted 1/30/04	None—This Technical Section is complete for walleye
Efficacy (pivotal/external columnaris disease/all freshwater-reared finfish except walleye)	AADAP (IAD #4000 & #9321)—Pivotal efficacy/external columnaris disease/all freshwater-reared finfish except walleye—being planned	None—pending acceptance
Efficacy (supplemental/external columnaris disease/all freshwater-reared finfish except walleye)	AADAP (IAD #4000 & #9321)—Supplemental efficacy/external columnaris disease/all freshwater-reared finfish except walleye—being planned	None—pending acceptance
Label (external columnaris disease/all freshwater-reared finfish)	AAC (IAD #8086) & NADA Coordinator—Label/external columnaris disease/all freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
FOI (external columnaris disease/all freshwater-reared finfish except walleye)	CVM—FOI/external columnaris disease/all freshwater-reared finfish except walleye—planned if efficacy accepted	None—pending acceptance
AOI (external columnaris disease/all freshwater-reared finfish)	AAC (IAD #8086) & NADA Coordinator—AOI/external columnaris disease/all freshwater-reared finfish—planned if efficacy accepted	None—pending acceptance
NADA Package (external columnaris disease/all freshwater-reared finfish except walleye)	AAC (IAD #8086) & NADA Coordinator—NADA package/external columnaris disease/all freshwater-reared finfish except walleye—planned if efficacy accepted	None—pending acceptance

4



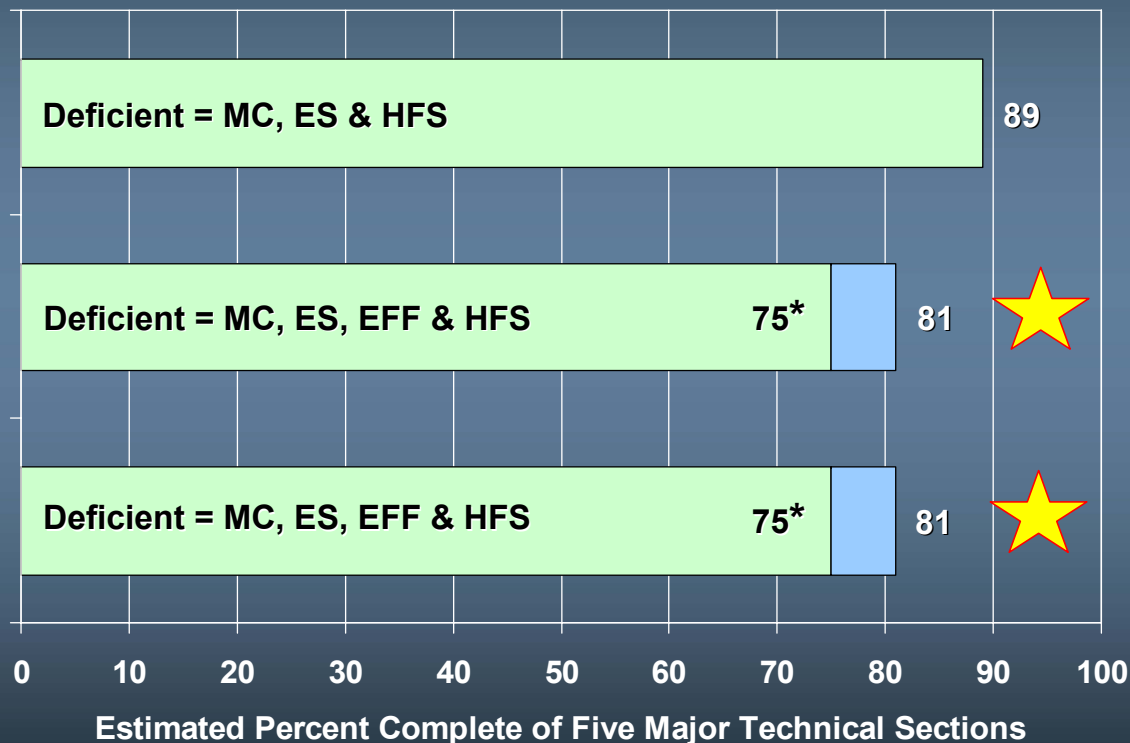
Approval Progress for Chloramine-T



BGD in FW salmonids
External columnaris in walleye

External columnaris in all other FW fish

BGD in all other FW fish





Approval Progress for Hydrogen Peroxide

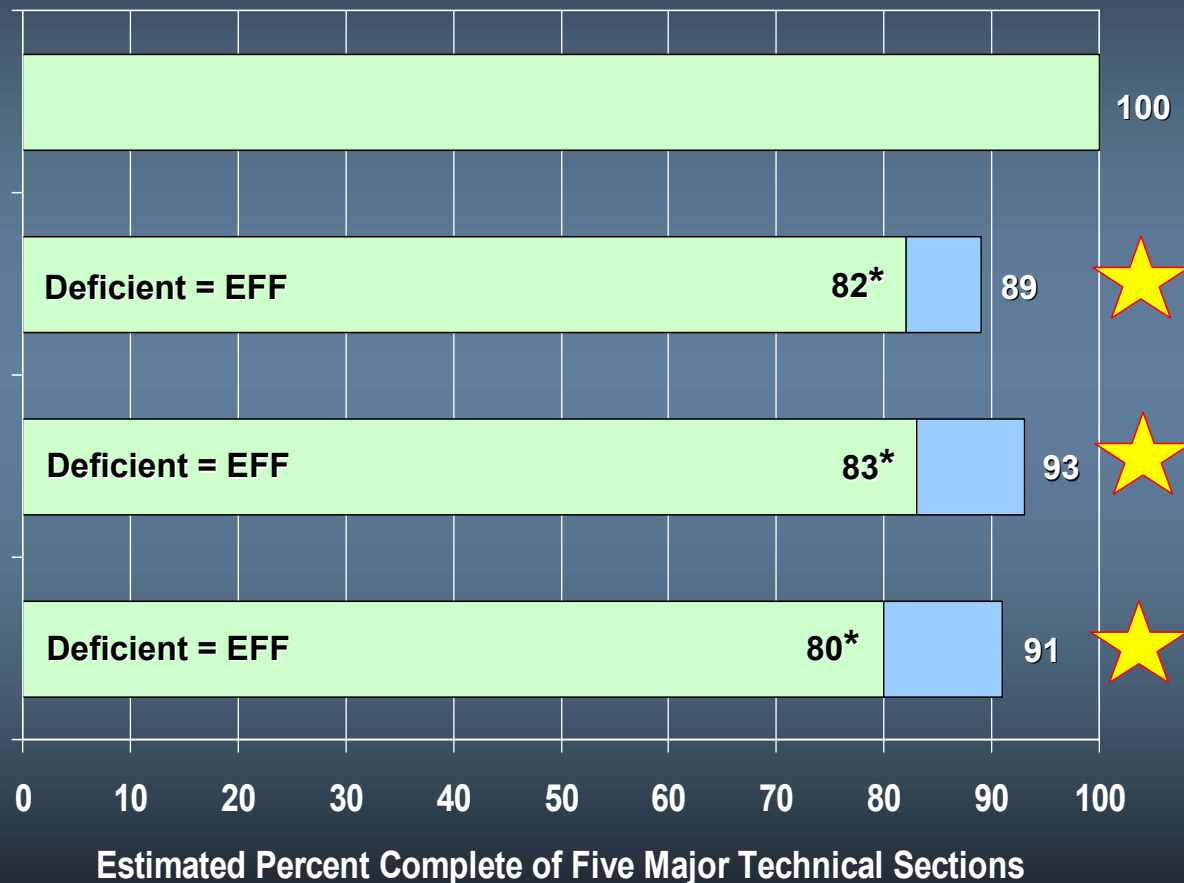


Saprolegnia in all FW fish eggs
BGD in FW salmonids
External columnaris in coolwater fish & CC

Saprolegnia in all FW fish

External columnaris in all remaining FW fish

External protozoa & monogenes in FW fish,
and control of mortalities from same





Approval Progress for Oral OTC

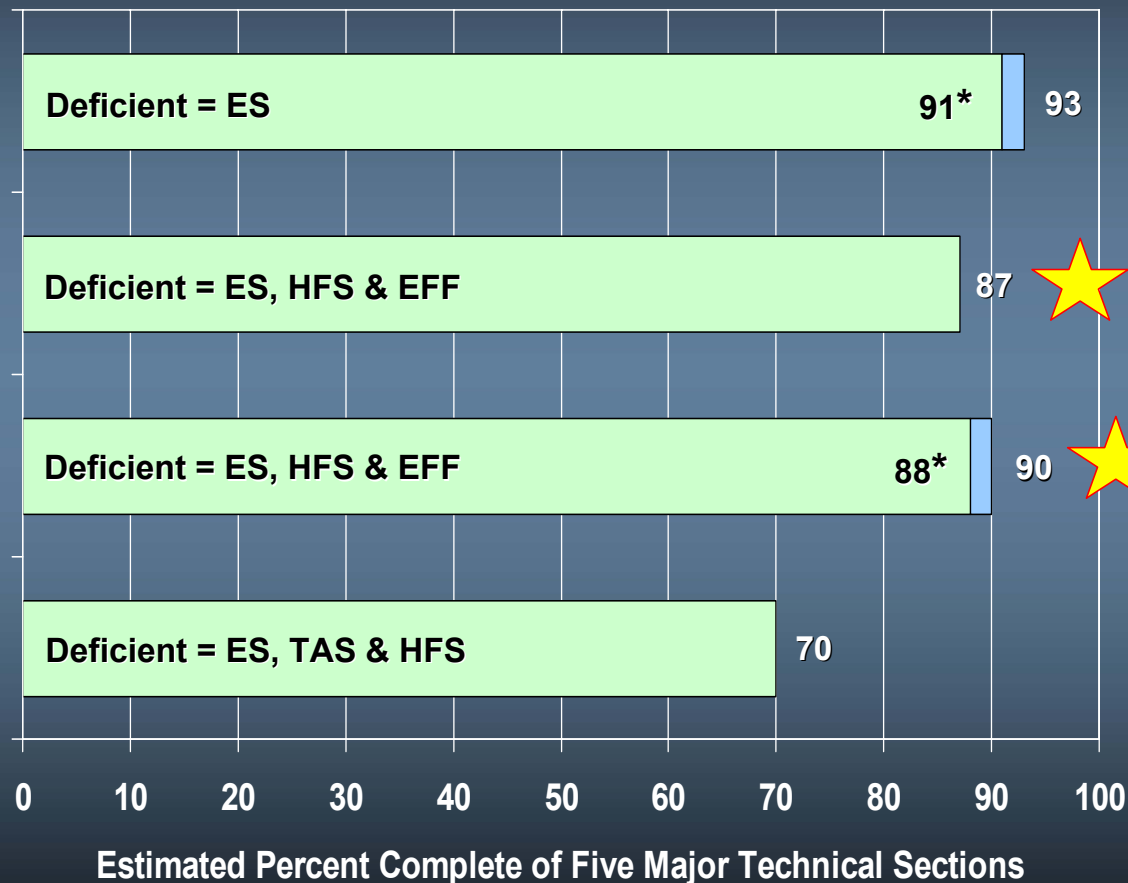


Systemic CWD in FW salmonids
Systemic columnaris in steelhead

Systemic columnaris in all other FW fish

Motile aeromonas septicemia in FW fish

Necrotizing hepatopancreatitis in shrimp

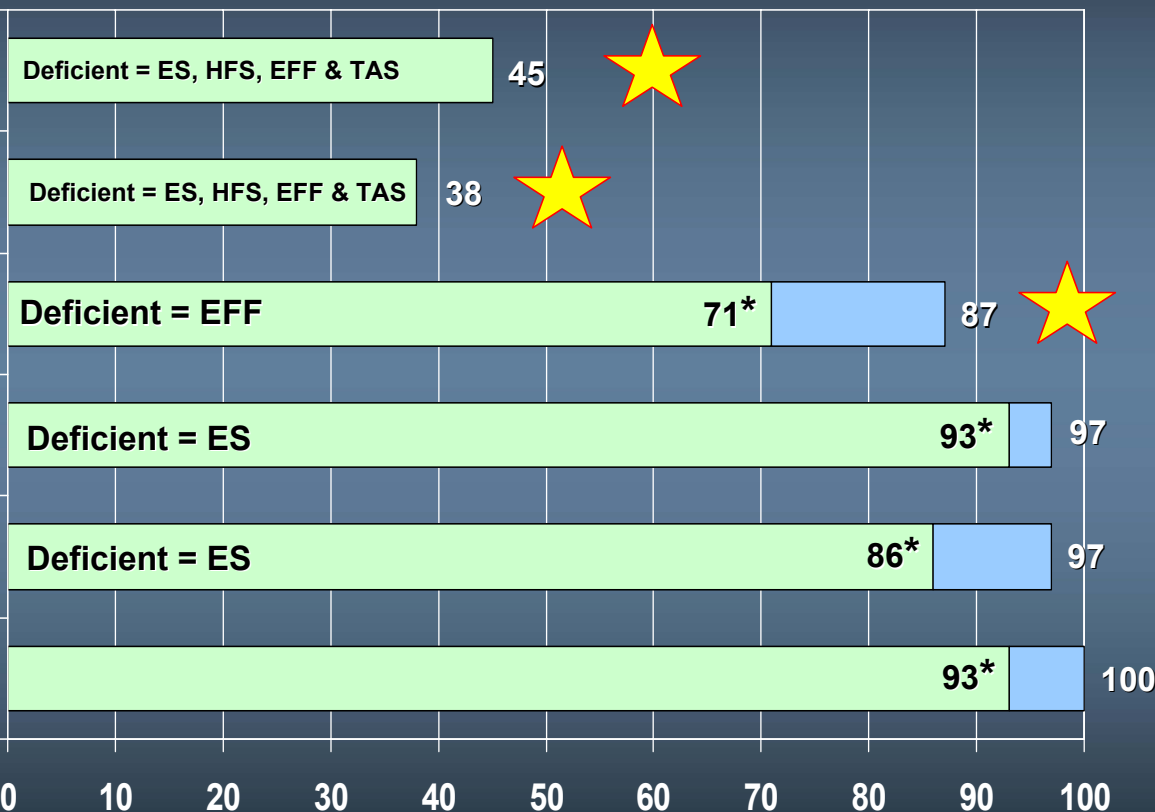




Approval Progress for Florfenicol



Streptococcal infections in tilapia



Streptococcal infections in hybrid striped bass

Systemic columnaris in channel catfish

Furunculosis in FW salmonids

Systemic columnaris in FW salmonids

CWD in FW salmonids

Estimated Percent Complete of Five Major Technical Sections



Approval Progress for AQUI-S®



Zero-withdrawal anesthetic for short-term handling of FW salmonids *

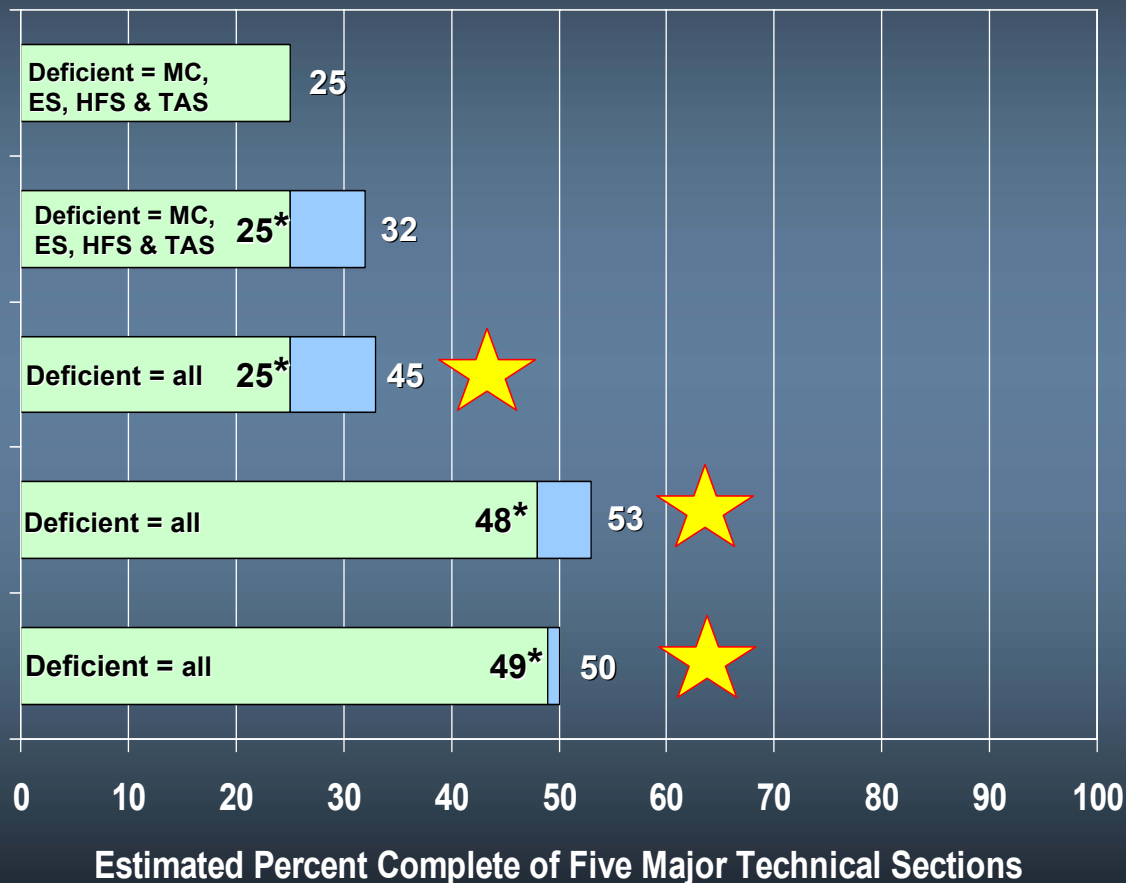
Zero-withdrawal anesthetic for short-term for cool & warmwater FW fish

Zero-withdrawal anesthetic for long-term handling of FW salmonids * #

Zero-withdrawal anesthetic for long-term handling of cool & warmwater FW fish

Zero-withdrawal anesthetic for short-term handling of marine fish and shellfish * #

- * = excludes Atlantic salmon HFS, EFF and TAS supportive work
= excludes short-term studies that may be applicable

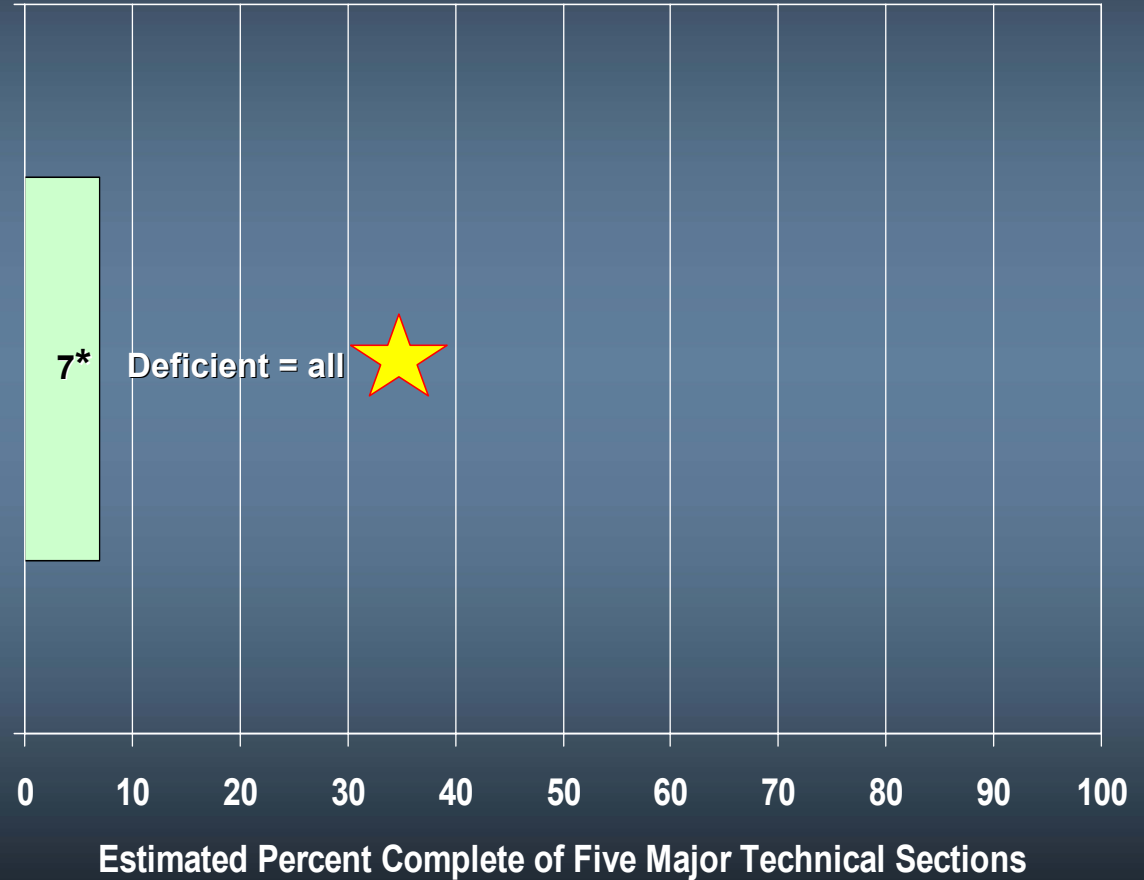




Approval Progress for SE-MARK[®] Immersion



Mass-marking of calcified tissue in larval fish





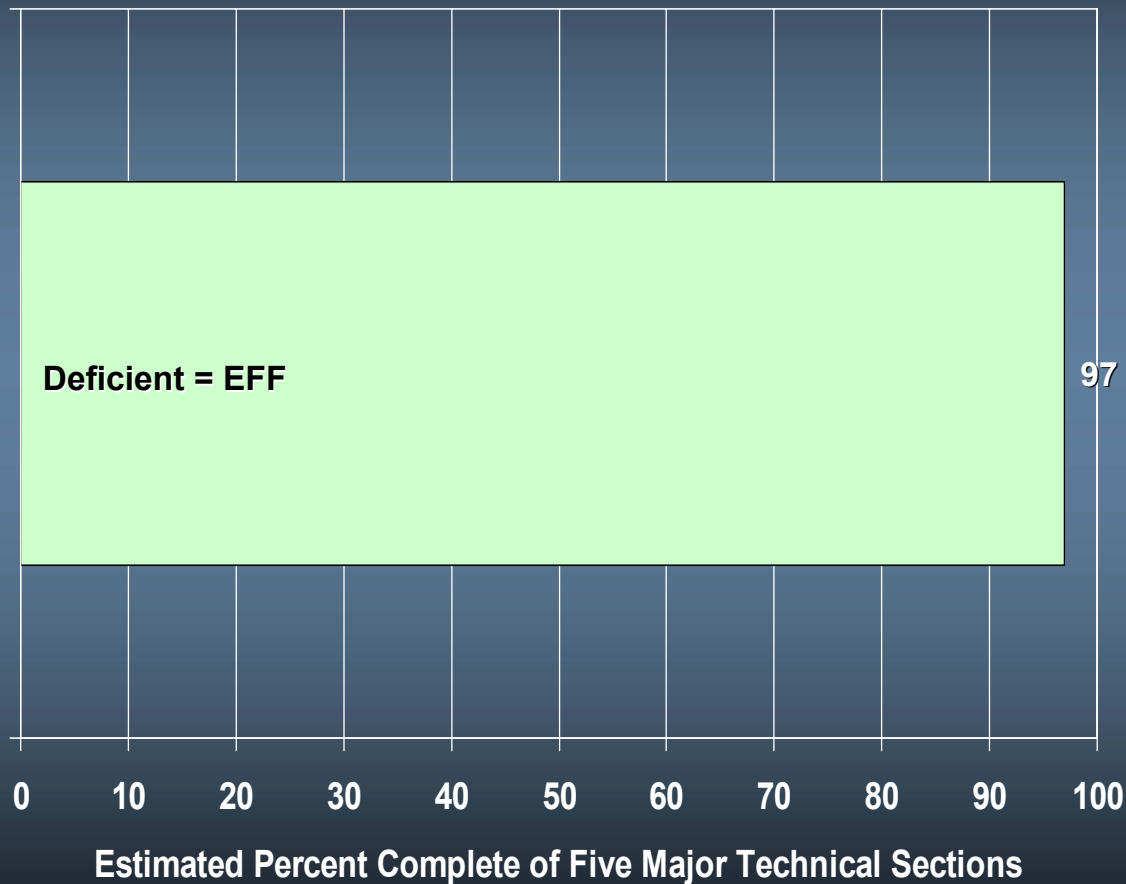
Approval Progress for Formalin



Saprolegnia in all FW fish

Deficient = EFF

97





Approval Progress for CuSO₄



Ichthyophthirius in channel catfish

Deficient = ES 87* 93

Ichthyophthirius in all other FW fish

Deficient = ES & TAS 73* 79

Saprolegnia in all FW fish eggs

Deficient = ES, TAS & EFF 50* 57

BGD in all FW fish

Deficient = ES, TAS & EFF 53* 60

External columnaris in all FW fish

Deficient = ES, TAS & EFF 53* 60

0 10 20 30 40 50 60 70 80 90 100

Estimated Percent Complete of Five Major Technical Sections



Approval Progress for KMnO₄



External columnaris in channel catfish

Deficient = all

45*



External columnaris in all other FW fish

Deficient = all

34*



BGD in FW salmonids

Deficient = all

31*



CWD in FW salmonids

Deficient = all

31*



External parasites in FW fish,
and control of mortalities from same

Deficient = all

31*



0 10 20 30 40 50 60 70 80 90 100

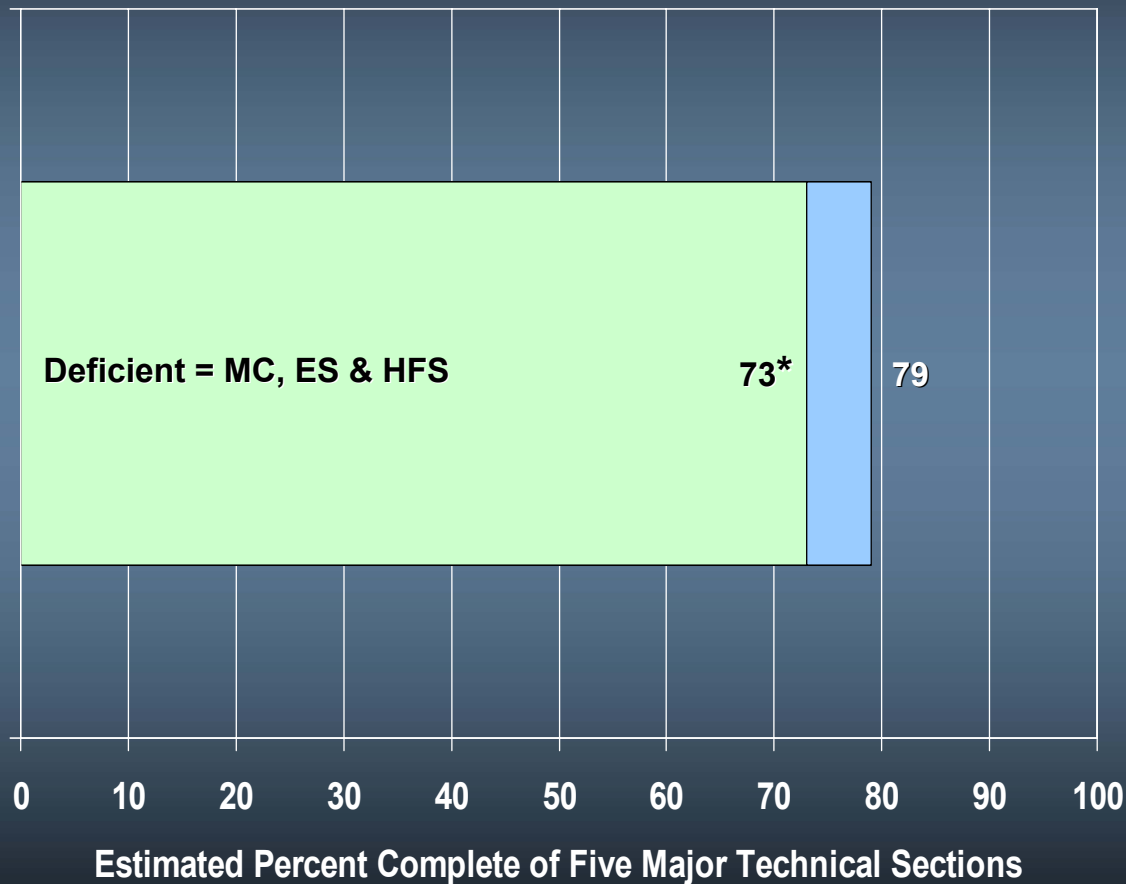
Estimated Percent Complete of Five Major Technical Sections



Approval Progress for Erythromycin

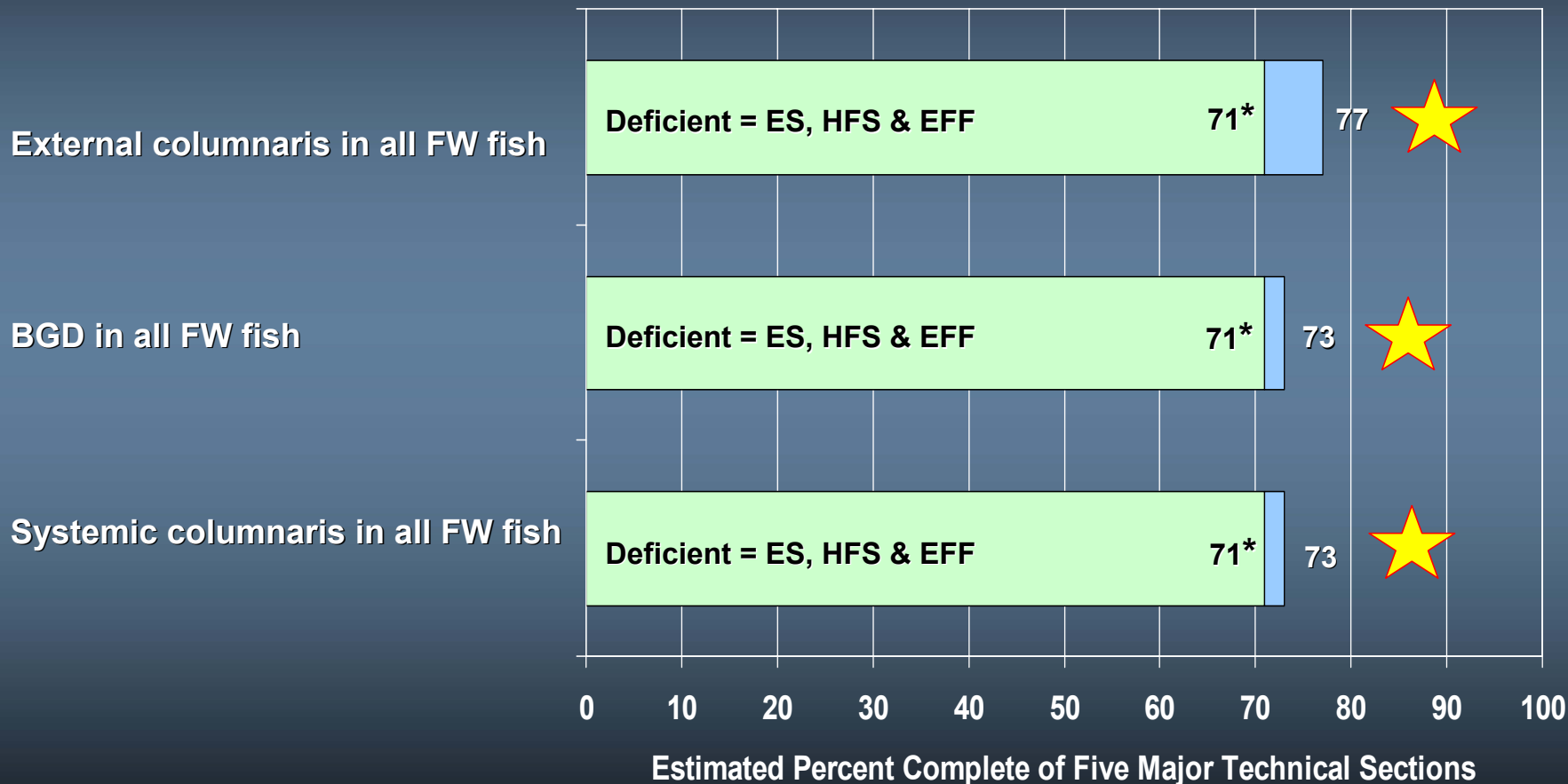


BKD in FW salmonids





Approval Progress for Immersion OTC





Approval Progress for 17 α -Methyltestosterone

Masculinization of early life-stage female tilapia

Deficient = MC, ES, EFF & TAS

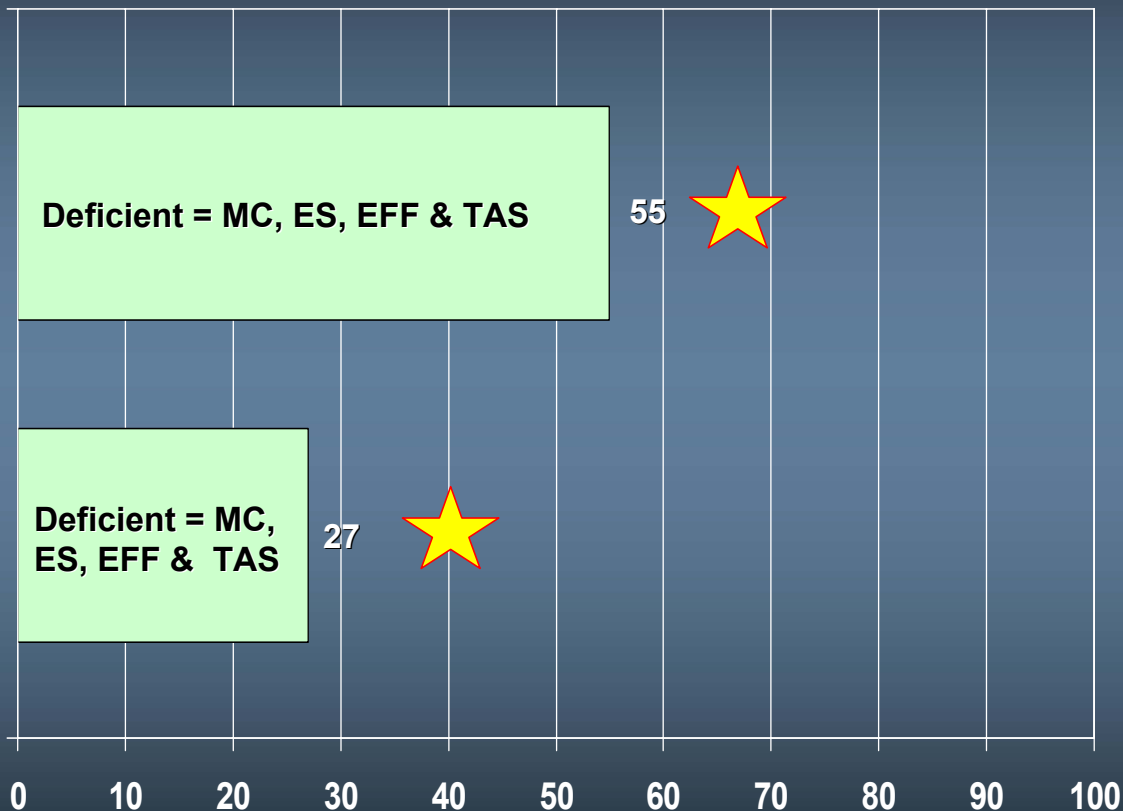
55



Gender manipulation in selected finfish
(e.g., salmonids, percids & ornamentals)

Deficient = MC,
ES, EFF & TAS

27



Estimated Percent Complete of Five Major Technical Sections



Approval Progress for Crude Carp Pituitary



Spawning Aid for all FW fish

